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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,260	04/22/2002	Paul Ernest Charles Brenchley	7397-3	6041

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EXAMINER	
COUNTS, GARY W	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 02/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/018,260	BRENCHLEY, PAUL ERNEST CHARLES	
	Examiner	Art Unit	
	Gary W. Counts	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities: The specification lacks a section entitled "BRIEF DESCRIPTION OF THE DRAWINGS". The application contains Figures 1 and 2 however, there is no section entitled "BRIEF DESCRIPTION OF THE DRAWINGS" nor is there any description of the drawings.

Appropriate correction is required.

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.
(b) CROSS-REFERENCE TO RELATED APPLICATIONS.
(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
(d) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or
REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)
(e) BACKGROUND OF THE INVENTION.
(1) Field of the Invention.
(2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(f) BRIEF SUMMARY OF THE INVENTION.
(g) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
(h) DETAILED DESCRIPTION OF THE INVENTION.
(i) CLAIM OR CLAIMS (commencing on a separate sheet).
(j) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).

(k) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-13, 15-17, 19 and 20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a solid phase support having immobilized thereon an HSGAG polymer having bonded thereto a first binding moiety and the list of molecules in claims 14 and 18, does not reasonably provide enablement for any and all paracrine cell regulators. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims are directed to a solid phase support having immobilized thereon an HSGAG polymer substrate having bonded thereto a first binding moiety and a paracrine cell regulator capable of binding to HSGAG, said first moiety and said paracrine cell regulator being capable of binding to a second moiety. The claims are also directed to a method of assaying a sample to determine heparanase activity by using the solid phase support.

The specification on page 4, lines 11-16 discloses the use of solid phase support having immobilized thereon an HSGAG polymer substrate having bonded thereto a first binding moiety and a paracrine cell regulator capable of binding to HSGAG, said first moiety and said paracrine cell regulator being capable of binding to a second moiety. However, it does not disclose the use of all paracrine cell regulators. The specification on page 5, lines 17 and 18 discloses the paracrine cell regulator may, for example, be a growth factor, cytokine or chemokine However, it does not disclose the use of all growth factors, cytokines or chemokines as paracrine cell regulators. Further, the term "paracrine cell regulator" is not an art recognized term and it is unclear what the term encompasses. The specification does not provide a definition for the term in the specification nor does it provide guidance of what the term encompasses. Also, the claims do not define what a paracrine cell regulator is. Therefore, one of ordinary skill in the art would not be inclined to know what a paracrine cell regulator is and thus the invention cannot be made or practiced without undue experimentation.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite because the preamble of the claims does not correlate with the body of the claim. The preamble of the claim recites a method of

assaying a sample to determine heparanase activity however, the body of the claim does not positively recite a step of determining heparanase activity.

Claim 1 is vague and indefinite because of the use of an acronym: ie HSGAG. Although the term may have art-recognized meanings, it is unclear if applicant intends to claim the prior art definitions. The term should be defined in its first instance. See also deficiency found in claim16.

Claim 1, line 7 "paracrine cell regulator" is vague and indefinite. It is unclear what the term encompasses. There is no definition provided for the term in the specification and the term is not an art recognized term.

Claim 1, line 7 "capable of" is vague and indefinite. The phrase "capable of" is not a positive limitation. It does not constitute a limitation in any patentable sense. See deficiencies throughout the claims.

Claim 1, part (iii) the recitation "the other of the first or second moiety" is vague and indefinite. It is unclear what applicant intends.

Allowable Subject Matter

6. Claims 14 and 18 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

7. The following is a statement of reasons for the indication of allowable subject matter: the prior art of record does not teach or fairly suggest a solid phase support or methods using the support wherein the solid phase support having immobilized thereon

an HSGAG polymer substrate having bonded thereto a first binding moiety and molecules as listened in claims 14 and 18.

The closes prior art is Nicolson et al (US 5,332,812). Nicolson et al discloses a method of determining heparanase activity in a sample (col 8, line 15 – col 10, line 34). However, Nicolson et al does not teach or fairly suggest molecules as listed in claims 14 and 18 also bound to the support.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Freeman et al (US 6,207,402) disclose a method of detecting mammalian heparanase activity in a sample (abstract, col 4, lines 15-45).

Freeman et al. (A rapid quantitative assay for the detection of mammalian heparanase activity) Biochem. J. (1997) 325, 229-237. Freeman et al disclose radiolabelled heparanase substrate and cHRG-Sepharose beads used in the methods.

Sewell et al. (Human mononuclear cells contain an endoglycosidase specific for heparan sulphate glycosaminoglycan demonstrable with the use of a specific solid-phase metabolically radiolabelled substrate) Biochem. J. (1989) 264, 777-783. Sewell et al disclose a solid-phase substrate having labeled glycosaminoglycans thereon for detection of endoglycosidases.

Nicolson et al (US 4,859,581) disclose a solid phase substrate which yields soluble labeled products upon hydrolysis by a glycosaminoglycan endoglycosidase. Nicolson et al discloses this substrate is used in the detection of heparanase levels.

Pecker et al (US 6,800,441) disclose heparanase specific molecular probes which can be used in research and medical applications (entire document).

Aster et al. (US 5,972,717) disclose a substrate having heparan sulphate immobilized thereon and also Platelet factor 4.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (571) 2720817. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gary Counts
Examiner
Art Unit 1641
January 31, 2005

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02/02/05